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EXAMINER

KOSAR, ANDREW D

ART UNIT PAPER NUMBER

1654

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 32, 33, 41 and 42, drawn to an article of manufacture and a dose form, classified in class 514, subclass 12.
- II. Claims 1-12 and 25-28, drawn to a method for treating a condition characterized by or involving, or that may be relieved in any measure by ameliorating, decreased β -cell mass and/or decreased β -cell number and a method of treating a disease, disorder or condition that is mediated in whole or in part by β -cells or β -cell dysfunction, classified in class 514, subclass 12.
- III. Claims 13-18, drawn to a method for increasing or maintaining β -cell mass and/or β -cell number, classified in class 514, subclass 12.
- IV. Claims 19-24, drawn to a method for stimulating growth in β -cell proliferation and/or increased β -cell mass, classified in class 514, subclass 12.
- V. Claims 29-31, drawn to a method of increasing insulin secretion in a subject, classified in class 514, subclass 12.
- VI. Claims 34-40, drawn to a method of making a medicament, classified in class 514, subclass 12.
- VII. Claims 43-58, drawn to a method of treating an injury or wound and a method of enhancing wound healing, classified in class 514, subclass 12.
- VIII. Claims 59 and 60, drawn to a an improved method of treating a condition in a subject, classified in class 514, subclass 12.

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- IX. Claim 61, drawn to administration of a composition, classified in class 514, subclass 12.
- X. Claims 62 and 63, drawn to a method of increasing insulin secretion in a subject, classified in class 514, subclass 12.
- XI. Claims 64 and 65, drawn to a method of improving the immune function in a subject, classified in class 514, subclass 12.

Please note, claims 34-40 and 61 do not have an active step and have been grouped separately. Claims 34-40 have been treated as a method of making.

The inventions are independent or distinct, each from the other because:

Invention VI is unrelated to inventions II-V and VII-XI. Inventions I and VI are unrelated.

Invention I is unrelated to inventions II-V and VII-XI.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06).

In the instant case, the different inventions (II-XI) have different steps and modes action and in practicing one method, one would not be practicing another. Invention VI is drawn to a method of making pharmaceuticals while the other methods are to administration of compounds.

Further, the product(s) of invention I are not made by the method of invention VI, as the method of invention VI does not have any active step. Additionally, the methods do not specifically require the use of the products of Group I.

Assuming arguendo that inventions I and VI are related as process of making and product made.

The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)).

In the instant case because the method has no active step, one could make the products by combining the required elements or assembling the article of manufacture.

Assuming arguendo that invention I is related to inventions II-V and VII-XI as product and process of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h).

In the instant case the product, as evidenced by the claims themselves, can be used in a variety of methods. Additionally, one could practice any of inventions II-V with GLP-1. One could practice invention VII with Neosporin. One could practice invention VIII with any of a myriad of compounds, as the method is a 'general' method, such as aspirin with caffeine for treating a 'condition' such as a migraine headache. One could practice invention IX with any compound, e.g. water. One could practice invention X with collagen, and one could practice invention XI with vitamin C.

Inventions II-V and VII-XI are directed to related methods using preptins, analogs, agonists, derivatives and salts thereof.

The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j).

In the instant case, the methods are not obvious variants of one another as each have different desired effects/outcomes and patient populations such that practicing one method one would not necessarily be practicing another.

The search for each of the above inventions is not co-extensive particularly with regard to the non-patented literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group.

Because these inventions are independent or distinct for the reasons given above, and the search for one invention would not necessarily lead to the discovery of another invention, restriction for examination purposes as indicated is proper, and to not restrict would be an undue burden on the Examiner.

Claims 1-65 are generic to the following disclosed patentably distinct species:

The claims are generic to a myriad of compounds defined by analogs, derivatives and agonists, too numerous to recite individually, including the recited species preptin (SEQ ID NOs:1-3) and the fragment [17-34]preptin (claim 4).

The species are independent or distinct because the claims recite only preptin, but no structure has been presented for the compounds defined as the analogs, derivatives and agonists, such that the compounds are defined by a common core structure essential for the utility. Thus, reciting no structure with a common core, the compounds of the instant application are distinct, absent evidence to the contrary, and would require a unique search strategy. The search for the distinct compounds is conducted based on their chemical structure. Therefore, the search of one chemical structure would not necessarily lead to the discovery of another structure, nor would it necessarily lead to the discovery of methods of using and/or making.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all

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claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Rejoinder

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Inventorship

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


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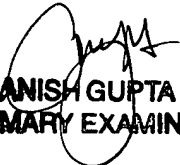
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571)272-0974. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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Art Unit 1654


ANISH GUPTA
PRIMARY EXAMINER